



Date: Monday, April 3, 2017 10:47:38 AM

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IRB_00098713

Created: 12/29/2016 4:06 PM

PI: Travis Maak MD

Submitted:

View: 1. Contacts and Title
Section: Contacts and Title

Title: The Effects of Pre-operative Evaluation Variables on Health Care Costs and Patient Outcomes Following Hip Arthroscopy

1. Contacts and Title

1. **Principal Investigator:**

Travis Maak

The Principal Investigator (PI) can create, edit, and submit IRB applications. The PI will also receive all study-related notifications from the ERICA system.

| Email | Training | Col Date |
|--------------------------|---------------|----------|
| travis.maak@hsc.utah.edu | 2/15/2017 SMG | 2/8/2017 |

a. **Position of Principal Investigator:**

Faculty

Student

Staff

Resident/Fellow

Other

If Other, describe:

b. **Will the Principal Investigator consent participants?** Yes No

2. **Contact Person(s) (if different from the PI):**

Contact persons have access to edit the IRB applications and receive all notifications from the ERICA system.

| Name | Email | Training |
|------------------|-------------------------------|--------------|
| Temitope Adeyemi | temitope.adeyemi@hsc.utah.edu | 5/21/2015 MG |
| Jaewhan Kim | jaewhan.kim@utah.edu | 1/14/2015 MG |
| Jennifer West | jennifer.west@hci.utah.edu | 9/22/2014 MG |

3. **Internal Staff and Sub-Investigator(s) (Within the University of Utah):**

Internal Staff and Sub-Investigators have read-only access to the IRB applications and do not receive notifications from the ERICA system. Add persons here who are responsible for the design, conduct, and reporting of research.

| Name | Email | Training | Obtaining Consent | Col Date |
|------------------|-------------------------------|--------------|--------------------------|-----------|
| Temitope Adeyemi | temitope.adeyemi@hsc.utah.edu | 5/21/2015 MG | <input type="checkbox"/> | 2/23/2017 |
| Jaewhan Kim | jaewhan.kim@utah.edu | 1/14/2015 MG | <input type="checkbox"/> | 1/27/2017 |
| Name | Email | Training | Obtaining Consent | Col Date |

4. External Sub-Investigator(s) (Investigators outside the University of Utah):

External Sub-Investigator cannot view applications in ERICA and will not receive study-related notifications from the ERICA system.

Last Name**First Name****Affiliation**

There are no items to display

5. Faculty Sponsor (if needed):

The Faculty Sponsor has read-only access to applications in ERICA and will receive all study-related notifications from the ERICA system.

6. Guests:

Guests can view applications in ERICA and will not receive study-related notifications from the ERICA system. If you need read Guest Access for an auditor or monitor, please contact the IRB at 801-581-3655.

Last Name**First Name****E-Mail**

There are no items to display

7. What type of application is being submitted?

New Study Application (or Amendment/Continuing Review)

8. Title Of Study:

Ensure the title matches those listed on the Protocol, Consent, and other appropriate documents.

The Effects of Pre-operative Evaluation Variables on Health Care Costs and Patient Outcomes Following Hip Arthroscopy

9. Study Purposes and Objectives:

The objectives should be stated in such a way that the reader can determine the appropriateness of the study design. If appropriate, state the specific hypotheses being tested and/or study aims. Use lay language.

The first objective of this study is to determine which pre-operative factors correlate with hip arthroscopy outcomes, specifically the need for additional procedures/interventions (e.g. revision arthroscopy, total hip arthroplasty, etc.)

Specific research questions include:

1. Hip arthroscopic outcomes

a. How do patient demographic data including:

- a. Age
- b. Gender
- c. Insurance status (Medicaid, Medicare, commercial, etc.)
- d. High deductible plan or not
- e. Rural vs. urban
- f. Comorbidity condition

b. Correlate with successful outcomes following hip arthroscopy as defined by required post-operative interventions including:

- a. Repeated injections
- b. Post-operative imaging
- c. Revision hip arthroscopy
- d. Total hip replacement

c. How does surgeon and facility volume correlate with successful outcomes following hip arthroscopy as defined by required post-operative interventions including:

- a. Repeated injections
- b. Post-operative imaging
- c. Revision hip arthroscopy
- d. Total hip replacement

2. Pre-operative evaluation

- a. How do the following pre-operative diagnostic techniques or absence of these techniques correlate with risk of failed hip arthroscopy
 - a. Plain radiographs (1 or 2 views) vs. (3 or more views)
 - b. MRI with arthrogram
 - c. MRI without arthrogram
 - d. CT scan
 - e. Intraarticular Hip injection
 - f. Back injection or SI joint injection
 - g. Psoas sheath injection
 - h. Physical therapy
3. What type of interventions occurred prior to or following hip arthroscopy including:
 - a. Gastrointestinal procedure (e.g. Hernia repair)
 - b. Urologic procedure (e.g. varicocele)
 - c. Gynecologic procedures (e.g. ovarian cyst removal, hysterectomy, etc.)
 - d. Other musculoskeletal procedures
 - a. Spinal procedures (lumbosacral fusion, disk herniation removal, epidural injections)
 - b. Iliosacral interventions (injections, fusions)

The second objective is to determine factors that influence the total cost of hip arthroscopy in Utah.

Specific research questions include:

4. Hip arthroscopy evaluation and intervention costs
 - a. How do the above pre-operative diagnostic techniques/interventions correlate with the total cost of care (i.e. inpatient cost + outpatient cost + medication cost)
 - a. e.g. Does pre-operative PT result in lower or higher cost of care?
 - b. How does surgeon and facility volume correlate with the total cost of care
 - c. Are surgical CPT codes utilized differently among surgeons or facilities
 - a. e.g. Do some facilities tend to use a certain CPT code more than others?
 - d. How does surgeon and facility volume correlate with surgical cost
 - e. How does the patient's insurance status correlate with cost of care

The third objective is to determine where patients requiring additional procedures/interventions after initial hip arthroscopy seek care

Specific research question:

5. Referral patterns
 - a. When patients require future surgical intervention (e.g. total hip replacement or revision hip arthroscopy), do they return to the initial surgeon (case A) or seek other surgeons/facilities (case B)?
 - a. Which factors (such as age, gender, high deductible plan or not, insurance status, comorbidity condition, prior type of interventions, rural vs urban, prior costs, etc.) are associated with case A or B?

10. Background and Introduction:

Identify the research area being studied and provide a review of the literature that provides the basis for understanding the objectives of the study. This review should be written such that scientists outside the investigator's area of expertise can understand the issues involved.

Any information about previous research related to this study involving animals and/or humans should be summarized. Include studies on pregnant animals if the research is conducted on pregnant women, fetuses, or neonates.

Hip arthroscopy is a surgical technique employed to diagnose and treat a wide variety of hip pathologies such as femoroacetabular impingement, chondral defects, labral tears, loose bodies, hip instability, and less severe forms of osteoarthritis, among others [1-3]. Because of its versatility in treating a number of hip conditions, its minimally invasive nature, and its relatively low complication rate, the frequencies of arthroscopic hip surgery has steadily increased in the last decade [4].

While good efficacy and increased patient satisfaction have been reported for arthroscopic procedures in particular populations [4], there continues to be debate among surgeons in regards to which patients and what disorders would benefit from the procedure [4,5]. Multiple factors have been associated with revision hip arthroscopy or failure of hip arthroscopy and conversion to total hip arthroplasty. These factors include persistent osseous structural pathology including acetabular dysplasia, pincer or cam deformity, labral deficiency, capsular instability and progression of underlying osteoarthritis. Many of these factors can be identified preoperatively and, theoretically, either avoided completely or addressed at the time of index surgery. Of particular interest among these are factors that influence indications to

proceed with hip arthroscopy and the complication and failure rates following arthroscopic intervention. For example, studies have found that conversions to total hip arthroplasty (THA) after hip arthroscopy are more likely to occur among older individuals and women, compared to cohorts that are younger or male [6]. Minimizing the need for revision surgery can significantly reduce health care costs and improve patient outcomes. However, aside from small case series, very little information is available on the aforementioned factors.

Physical therapy is one such costly pre-operative intervention that is required by some but not all insurance companies prior to hip arthroscopy. However, to the authors' knowledge, there has never been a study that has demonstrated the efficacy of physical therapy in treating femoroacetabular impingement. On the other hand, other pathologies that cause hip pain such as iliopsoas tendinitis can be easily treated with PT. Fortunately, pre-operative evaluation using MRI, CT scan, and guided intraarticular injection can easily differentiate among these pathologies and possibly eliminate the need for unnecessary and costly surgery or pre-operative physical therapy. The all payers database provides the unique opportunity to evaluate these data and correlate these preoperative interventions with post-operative revision rates and subsequent interventions. These correlations should provide important insights into (1) which interventions or evaluation techniques are associated with reduced post-operative interventions including intraarticular injections and revision surgeries, among others and (2) the cost of these interventions.

To the authors' knowledge, no information exists regarding the incurred health care costs of preoperative and post-operative evaluation methods or revision surgeries. Little research has been done to evaluate which conservative therapies and pre-operative diagnostic techniques have been utilized and their correlation to surgical outcomes and healthcare costs. Understanding these relationships should improve the ability of treating physicians to determine the most cost-effective and useful pre-operative diagnostic techniques and identify important factors that may reduce post-operative interventions including revision hip arthroscopy or conversion to total hip arthroplasty.

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Created: 12/29/2016 4:06 PM

PI: Travis Maak MD

Submitted:

Title: The Effects of Pre-operative Evaluation Variables on Health Care Costs and Patient Outcomes Following Hip Arthroscopy

View: 2. Location and Sponsor Study Location and Sponsors
Section: Location and Sponsors

2. Study Location and Sponsors

1. Select the location(s) applying for approval of research via the University of Utah Human Research Protection Program (HRPP) and/or IRB:

University of Utah's Covered Entity (Health sciences, hospitals, and clinics)

1. Add other external locations applying for approval of research via the University of Utah HRPP and/or IRB:

If the University of Utah IRB will be the central or single IRB for the study, add all locations that will be covered. If the name of the organization does not appear, contact the IRB.

If the location is supporting the research, but does not need IRB approval to cover their activities (i.e., the location is not 'engaged in research'), add the name of the site to the Resources and Responsibilities page instead.

| Site Name | Site Investigator | Investigator/Main Contact | Procedures | Other Site |
|-------------------------------|-------------------|---------------------------|------------|------------|
| There are no items to display | | | | |

2. Indicate the lead site. Select N/A if there is no lead site.

If the name of the organization does not appear, contact the IRB.

- N/A
- Explain:

3. Select the University of Utah department responsible for this research:

ORTHOPEDIC SURGERY

2. Will a Central IRB (CIRB) or Single IRB (SIRB) model be used for review of this study?

Study team members must have documented training for use of a CIRB/SIRB model prior to IRB approval of a new study. Visit the IRB website for more information.

Yes No

3. Indicate the source(s) of funding obtained or applied for to support this study.

| Sponsor | Sponsor Type | Sponsor Contact Information |
|-------------------------------|--------------|-----------------------------|
| There are no items to display | | |

4. Does this study have functions assigned to a Contract Research Organization (CRO)?

Yes No

If yes, CRO Contact Information:

Name, address, phone number, fax number used for study correspondence.

5. Does this study involve use of the Utah Population Database (UPDB)?

Yes No

If yes, approval from the Resource for Genetic and Epidemiologic Research (RGE) (801-581-6351) is required before final IRB approval. Complete the RGE application on the "Ancillary Committees" page of the IRB application.

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Created: 12/29/2016 4:06 PM

View: 3. Participants

PI: Travis Maak MD

Submitted: Section: Participants

Title: The Effects of Pre-operative Evaluation Variables on Health Care Costs and Patient Outcomes Following Hip Arthroscopy

3. Participants

1. Ages of Participants:

7 to 17 years old (Parental permission and assent form needed)

18 and older (Consent form needed)

2. Specific age range of participants (e.g., 7-12 years old, 60+, etc.):

14+

3. Indicate any vulnerable participant groups (other than children) included:

Select only those groups which you are specifically studying or which have a high likelihood of being included in this project.

None

If "Other", please specify:

If "None" and no children are involved, answer the following question.

Has the participant selection process overprotected potential subjects who are considered vulnerable so that they are denied opportunities to participate in research?

Yes No

4. Number of participants to be enrolled during the entire study:

Provide specific numbers if possible. Use of records and databases containing human information should also be considered in the number of participants.

At Utah: 4000

All Centers:4000

5. Characteristics of Participants/Inclusion Criteria:

Participant-entry criteria should be as detailed as necessary to define the participant population under study and, for clinical studies, to reduce confounding treatments or diseases. Precise criteria for age, gender, or another other factors (e.g. diagnoses, extremes in signs or symptoms, etc.) should be included.

All patients who have undergone hip arthroscopy in Utah with information contained in the All Payors Claims Database (APCD) are eligible for inclusion. Hip arthroscopy patients will be identified with the following CPT codes:

- 29862
- 29916
- 29915
- 29914
- 29861
- 29999

The following variables will be collected from the APCD:

eligibility file: patient ID, insurance effective date and end date, insurance type, coverage level, gender, date of birth (month/year only), urban/rural designation, race/ethnicity, coverage type, group size, risk basis, high deductible

Medical claims file: patient id, gender, urban/rural designation, date of birth (month/year only), CPT/HCPCS codes, ICD diagnosis and procedure codes, provider specialty, provider ID (or NPI), provider urban/rural designation, type of bill, date of service, paid amount, co-pay, co-insurance, deductible amount, admission date, discharge date, DRG

Pharmacy claims file: patient id, pharmacy number, pharmacy urban/rural designation, NDC, new prescription or refill, generic drug indicator, quantity dispensed, days supply, paid amount, ingredient cost, dispensing fee, copay, coinsurance, deductible

Provider file: provider ID (or NPI), provider specialty, urban/rural designation

All dates requested will included only month and year rather than full date.

6. Participant Exclusion Criteria:

Specific exclusion criteria should be listed which could interfere with the study design or place a participant at risk during the study. If no exclusion criteria, please state "None."

Incomplete records in the APCD will exclude participation.

7. Is a substantial percentage of the participant population anticipated to be non-English speaking?

If the question is not applicable (e.g., chart or record review), please select "no."

Yes No

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Created: 12/29/2016 4:06 PM

View: 3.5
Vulnerable
Populations

PI: Travis Maak MD

Submitted:

Title: The Effects of Pre-operative Evaluation Variables on Health Care Costs and Patient Outcomes Following Hip Arthroscopy

Section: Vulnerable
Populations

Vulnerable Populations

Justification Requirements for the Inclusion of Vulnerable Populations

- 1. How does the nature of the research require or justify using the proposed subject population?**
Hip arthroscopy is an increasingly popular surgical technique used to diagnose and treat many hip related concerns that do not respond favorably to conservative treatment. Many of the hip conditions effectively treated with hip arthroscopy also occur in skeletally mature adolescents (typically aged 14+). Understanding what factors influence the success rate of hip arthroscopy may provide further guidance to surgeons treating both adolescent and adult patients.
- 2. Would it be possible to conduct the study with other, less vulnerable subjects?**
 Yes No
If yes, justify the inclusion of vulnerable subjects:
- 3. Is this population being included primarily for the convenience of the researcher?**
 Yes No
If yes, explain:
- 4. Does the scientific merit of the study warrant the inclusion of subjects who may either be susceptible to pressure or who are already burdened?**
 Yes No

IRB_00098713

Created: 12/29/2016 4:06 PM

View: 4. Study Information

PI: Travis Maak MD

Submitted:

Section: Study Information

Title: The Effects of Pre-operative Evaluation Variables on Health Care Costs and Patient Outcomes Following Hip Arthroscopy

4. Study Information

1. Design of Study (select all that apply):

Secondary/Archival Data Analysis

If Other, describe:

2. Does your study involve the use of any placebo?

Yes No

3. Length of entire study, from initiation through closeout:

Include the amount of time expected to enroll participants and complete all data analysis.

5 years

4. How will participants be recruited or identified for inclusion in the study?

The IRB does not allow cold-calling as a method of recruitment. All recruitment materials must be attached to the Documents and Attachments page.

a. Select all methods that will be used:

Written or electronic record review

b. Describe the recruitment/participant identification process in detail (e.g. who will review charts or records, who can refer participants to the study, where will flyers be posted, how often will recruitment letters be sent, when will follow-up phone calls be made, etc.):

Indicate that participants will not be contacted if the study only involves a waiver of informed consent for a retrospective chart/data review.

Patients will be identified in the All Payor Claims Database (APCD) using submitted CPT codes from 2013-2015:

- 29862
- 29916
- 29915
- 29914
- 29861
- 29999

5. How will consent be obtained?

If your study uses deception, attach the consent document and debriefing statement to the Documents and Attachments page. Check both Informed Consent Process and Waiver or Alteration of Informed Consent.

Waiver or Alteration of Informed Consent

Alteration of consent requests that required element(s) of consent template be removed or altered (e.g. use of deception in consent)

6. Describe all the procedures chronologically, from screening/enrollment through study closeout, which will be completed in the research project.

The investigational activities, treatments, or procedures must be clearly detailed as to how and when they will be performed. For clinical studies, this includes study visits, drug treatments, randomization, and the procedures that are part of standard of care. For clinical studies, a distinction should be made between the procedures for treatment evaluation

versus procedures for safety evaluation. Treatment endpoints must be defined as well as interim procedures for dealing with adverse events.

The study is requesting access to APCD data, which will be obtained from the Utah Population Database (UPDB). No other UPDB data is being requested. A table of requested APCD fields is attached in Documents and Attachments (highlighted fields). Upon approval from the Utah Health Data Committee, Pedigree and Population Resource (PPR) staff at UPDB will pull APCD data for the study team based on the requested fields and the following CPT Codes:

- 29862
- 29916
- 29915
- 29914
- 29861
- 29999

No identifiable information is being requested. All dates requested will include only month and year rather than full date. PPR will provide urban/rural designation in place of zip code data.

PPR will provide unique substitute ID numbers for the following: Member_ID, Person_ID, Provider_Aux_ID and Payer_Cd.

7. Are all procedures for research purposes only (non-standard or non-standard of care procedures)?

Yes No

If no, list the procedures that are performed for research purposes only (non-standard or non-standard of care procedures):

If the study is conducted at the VA, you must also indicate who is responsible for research care and who is responsible for non-research care.

8. Is there a safety monitoring plan for this study?

All studies determined by the IRB to be more than minimal risk must have a safety monitoring plan. Click Help for more information about risk and safety monitoring plans.

Yes No

9. Provide a summary of the statistical methods, data analysis, or data interpretation planned for this study. Factors for determining the proposed sample size (e.g., power) should be stated.

Descriptive statistics, including measures of central tendency and dispersion, will be computed for continuous data, and frequency distributions will be estimated for binary or categorical variables. Bayesian network model or probabilistic directed acyclic graphical model will be used to examine conditional dependencies of variables (including outcomes and independent variables).

1.Objective 1:

a. Outcomes in Aim 1-3 will be binary (yes or no) so that logistic regression will be used to estimate the odds ratios of factors of interest. There could be clustering effects because some patients could see or have treatment within same facility or same doctor, and these clustering effects will be reflected in standard error calculations (i.e. robust standard errors).

2.Objective 2:

a. Aim 4: Twelve months following pre-operative diagnostic techniques / interventions will be considered for healthcare cost and utilization (i.e. more procedure use). Total healthcare costs in Aim 4 will be the sum of inpatient, outpatient (including emergency department) and medication costs. Because we will use the 2013-2015 APCD data, the cost will be adjusted to 2015 dollars using Medical care price indices (www.bls.gov/cpi/). To find out factors that affect healthcare costs over 12 months following interventions, the generalized linear model with the gamma distribution and the log link function will be used to reflect that cost data are typically positively skewed by some patients with very high costs. When many patients have zero cost, two-stage modeling for cost estimation will be performed. To find out which CPT code is used more in some facilities, we will check frequency of all CPT codes of interest and run logistic regressions.

3.Objective 3:

a. Aim 5: We will identify whether or not patients visit the initial surgeon/facility during 12 months followup from initial procedures/interventions. Provider/facility information will be identified from the APCD using facility ID and provider ID. The outcome variable will be binary (i.e. initial surgeon/facility or different surgeon/facility) so that logistic regression will be used to estimate odds ratios of factors of interest.

IRB_00098713

Created: 12/29/2016 4:06 PM

PI: Travis Maak MD

Submitted:

View: 4.1 Request for Waiver or Alteration of Consent
Section: - Request for Waiver of Consent

Title: The Effects of Pre-operative Evaluation Variables on Health Care Costs and Patient Outcomes Following Hip Arthroscopy

Request for Waiver or Alteration of Consent

Instructions:

- Click "Add" below to add a new waiver request to this application.
- Click the waiver name link to edit a waiver that has already been created.
- To delete a waiver request, contact the IRB.

*** Requested Waivers**

| Date Created | Type of Request | Purpose of Waiver Request |
|---------------------------------|--|---|
| View 12/29/2016 | Waiver of Informed Consent <i>(no contact with participants and no documentation of consent, e.g. chart or record review)</i> | Database review for all data collection |

IRB_00098713

Created: 12/29/2016 4:06 PM

View: IRB Smart Form

PI: Travis Maak MD

Submitted:

- Request for Section: Waiver of Consent

Title: The Effects of Pre-operative Evaluation Variables on Health Care Costs and Patient Outcomes Following Hip Arthroscopy

Request for Waiver or Alteration of Consent

1. Purpose of the Waiver Request:

Briefly state or summarize the purpose of this waiver (e.g., chart review for all data collection, removing a consent element, using deception procedures, etc.)

Database review for all data collection

2. Type of Request:

Waiver of Informed Consent

a. Will deception be used? Yes No

If yes, provide the rationale and describe the debriefing procedures:

3. List the identifying information you plan to collect or keep a link to (e.g. names, dates, or identification numbers such as social security numbers or medical record numbers, etc.).

- Patient ID
- DOB
- Race/ethnicity
- Gender
- Insurance type
- CPT codes
- ICD diagnosis and procedure codes
- urban/rural designation

A table of requested APCD fields is attached in Documents and Attachments (highlighted fields). No identifiable information is being requested. All dates requested will include only month and year rather than full date. PPR will provide urban/rural designation in place of zip code data.

PPR will provide unique substitute ID numbers for the following: Member_ID, Person_ID, Provider_Aux_ID and Payer_Cd.

4. Explain why the research could not practicably be conducted without the waiver or alteration. For example, complete the following sentence "If I had to obtain consent, the research could not be conducted because...":

- *Example: "If consent were a requirement, the investigator would be unable to obtain consent for about 30% of participants because they have moved and lost to follow-up and the contact information in our database is incorrect. With a loss of 30% of participants, the investigator would be unable to answer the research question."*
- *Example: "If consent were a requirement, the investigator would have to obtain consent on about 100,000 individuals which would require about 10 years of time for the two person staff to accomplish assuming that the staff spend 50% of their time on obtaining consent. The degree of effort would make it not practicable to conduct the research."*

Because we are looking at all patents undergoing hip arthroscopy in the state of Utah (including outside of the University of Utah health system) from 2013-2015, the degree of effort would make it not practicable to conduct the research.

5. Explain why the research and privacy risk of the research are no

more than *minimal*:

- *Example: "because the main risk is a breach of confidentiality and procedures are in place to make such breaches very unlikely."*
- *Example: "because the review of subjects' medical records is for limited information and is not sensitive in nature."*

because the main risk is a breach of confidentiality and procedures are in place to make such beaches very unlikely.

6. Describe the measures you will take to ensure the waiver or alteration will not adversely affect the rights and welfare of the subjects:

- *Example: "because the information was collected for clinical care and the research will not change the care the individual received."*
- *Example: "because the information collected is not sensitive and a reasonable person who is in the participant's position would not consider the waiver as adversely affecting his/her rights."*

because the information was collected for clinical care and the research will not change the care the individual received

7. Explain how you will, if applicable and appropriate, provide the subjects with additional pertinent information after they have participated in the study, or indicate "*Not applicable*":

- *Example: "Providing participants pertinent information after participation is not appropriate as the results would have no effect on the individuals."*
- *Example: "Providing participants pertinent information after participation is appropriate because deception was used and the participants should be debriefed according to the investigator's protocol."*

Not applicable

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Created: 12/29/2016 4:06 PM

PI: Travis Maak MD

Submitted:

View: 5. Data Monitoring Plan
Section: Data Monitoring

Title: The Effects of Pre-operative Evaluation Variables on Health Care Costs and Patient Outcomes Following Hip Arthroscopy

5. Data Monitoring Plan

The purpose of data monitoring is to ensure the integrity of the research data, adherence to the approved research plan, and that privacy and confidentiality risks are minimized. The complexity of a data monitoring plan depends on the complexity and risk of the study. You should design a monitoring plan that is suitable and realistic for your project. The IRB has self-assessment forms available for biomedical and social/behavioral studies to guide you through the monitoring process: <http://irb.utah.edu/a-z.php>

- 1. **Privacy Protections:** Privacy refers to persons and to their interest in controlling access of others to themselves. Privacy can be defined in terms of having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. **What precautions will be used to ensure subject privacy is protected?**

Select all that apply:

The collection of information about participants is limited to the amount necessary to achieve the aims of the research, so that no unneeded information is being collected
(can be used for research with no participant contact, e.g., chart reviews or secondary data analysis)

Other or additional details (specify):

- 2. **Confidentiality Precautions:** Confidentiality is an extension of the concept of privacy; it refers to the subject's understanding of, and agreement to, the ways identifiable information will be stored and shared. Identifiable information can be printed information, electronic information or visual information such as photographs. **What precautions will be used to maintain the confidentiality of identifiable information?**

Select all that apply:

Storing research data on password protected computers or in locked cabinets or offices

Participant identifiers will be stored separately from the coded, participant data

All data that will be transferred or transported outside of the institution will be encrypted

Other or additional details (specify):

- 3. **Will photos, audio recordings, or video recordings, or medical images of participants be made during the study?**

Select "No" if medical images are made for standard of care purposes.

Yes No

If yes, describe the recording/images and what will become of them after creation (e.g., shown at scientific meetings, stored in the medical/research record, transcribed, erased, etc.):

- 4. **How will study data and documentation be monitored throughout the study?**

Select all that apply:

Confirmation that all appropriate information has been reported to the sponsor, oversight agencies (such as the FDA), and/or IRB

Other additional details (specify):

- 5. **Who will be the primary monitor of the study data and documentation?**

Select all that apply:

Principal Investigator

Study Coordinator or Research Nurse

Other or additional details (specify):

6. How often is study data and documentation monitoring planned (e.g., monthly, twice a year, annually, after N participants are enrolled, etc.)?

Data will be monitored periodically throughout the study as data is analyzed by the statistician and prior to publishing of the manuscript. Data will be monitored prior to study closeout by coordinator.

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Created: 12/29/2016 4:06 PM

PI: Travis Maak MD

Submitted:

View: 6. Risks
and
Benefits
Risks
Section: and
Benefits

Title: The Effects of Pre-operative Evaluation Variables on Health Care Costs and Patient Outcomes Following Hip Arthroscopy

6. Risks and Benefits

1. Describe the reasonable foreseeable risks or discomforts to the participants:

Only include the risks of research-related procedures.

there may be a small risk of loss of confidentiality.

2. Describe the potential benefits to society AND to participants (do not include compensation):

There are no direct benefits to participants included in this study. However, determining what factors correlate to the success or failure rate of hip arthroscopy as well as associated costs may benefit orthopaedic surgeons and their patients in the future.

3. Are there any costs to the participants from participation in research?

Yes No

If yes, specify:

4. Is there any compensation to the participants?

Yes No

a. **If yes, answer the following:**
Specify overall amount:

b. **Specify when participants will be paid (e.g. at each visit, at end of study, etc.):**

c. **If applicable, please specify payment by visit or other time interval (e.g. \$10 per visit, etc.):**

d. **If applicable, explain plan for prorating payments if participant does not complete the study:**

IRB_00098713

Created: 12/29/2016 4:06 PM

View: 7. HIPAA

PI: Travis Maak MD

Submitted:

HIPAA and
Section: the Covered
Entity

Title: The Effects of Pre-operative Evaluation Variables on Health Care Costs and Patient Outcomes Following Hip Arthroscopy

7. HIPAA and the Covered Entity

1. Does this study involve Protected Health Information (PHI) or de-identified health information?

Yes No

a. If yes, select the method(s) of authorization that will be used:

Waiver or Alteration of Authorization

(If you are using medical records for screening or recruitment, please request a Waiver of Authorization)

If needed, select De-Identification Form:

b. If yes, will PHI be disclosed outside the Covered Entity?

Yes No

If so, to whom?

And for what purposes?

2. Does this study involve any of the following:

a. The investigational use of a drug?

Yes No

b. The investigational use of a medical device?

Yes No

If medical device requires an IDE or HDE, approval from CMS: Center for Medicare and Medicaid Services is required after final IRB approval is obtained prior to enrolling any Medicare participant.

<http://healthsciences.utah.edu/crce/device/index.php>

c. Is this an investigator-initiated drug or device trial lead by the Principal Investigator?

Yes No

All investigator-initiated drug or device trials are required to have a full research protocol attached to the Documents and Attachments page.

d. Exposure to radioisotopes or ionizing radiation?

Yes No

If yes, approval by the Radioactive Drug Research Committee and Human Use Subcommittee (RDRC-HUS) (801-581-6141) is required before final IRB approval. Complete the RDRC-HUS application on the "Ancillary Committees" page of the IRB application.

e. Does the study involve cancer patients and/or address a cancer question?

Yes No

Answering 'Yes' to this question will bring your study before the Huntsman Cancer Institute Protocol Review and Monitoring Committee (801-585-6746) for review (prior to IRB approval) and make it eligible for NCI annual reporting. Complete the HCI PRMC application on the HCI PRMC New Project Cover Sheet page of the IRB application.

f. Any component of the Center for Clinical and Translational Science (CTS)?

This includes any non-clinical support, such as biostatistical services. To request these services, you must submit a form outside of the ERICA system. Click here to submit this form.

Yes No

The Clinical Services Core (CSC)?

This is the CCTS venue for inpatient and outpatient human subjects studies. You will be required to complete the CSC application in the ERICA system, which will appear later as you continue through this application.

Yes No

g. A Humanitarian Device Exemption (HDE)?

Yes No

If yes, please attach a copy of the letter from the FDA granting the HDE. If medical device requires an IDE or HDE, approval from CMS: Center for Medicare and Medicaid Services is required after final IRB approval is obtained prior to enrolling any Medicare participant. <http://uuhsc.utah.edu/clinicaltrials/Device/index.html>

h. Genetic testing and/or analysis of genetic data?

Yes No

For more information about conducting genetic research, review the guidance document titled Genetic Research available at <http://irb.utah.edu/guidelines/investigator.php>

i. Creating or sending samples to a tissue bank/repository?

A tissue bank/repository is established to collect, store, and share tissues for analysis and use in future research projects.

Yes No

j. The use of human subjects and biological agents (e.g., staphylococcus aureus, adenovirus), the collection of samples from individuals infected with biological agents (e.g., blood or tissue samples from hepatitis B virus-positive patients), or the deliberate transfer of recombinant DNA vectors/plasmids (recombinant DNA, or DNA or RNA derived from recombinant DNA) or synthetic DNA into human research participants?"

Yes No

If yes, please attach an approval letter from the University of Utah Institutional Biosafety Committee (IBC), biosafety@ehs.utah.edu or 801-581-6590.

IRB_00098713

Created: 12/29/2016 4:06 PM

View: 7.1 Request
Waiver of
Authorization
- Request for
Section: Waiver of
Authorization

PI: Travis Maak MD

Submitted:

Title: The Effects of Pre-operative Evaluation Variables on Health Care Costs and Patient Outcomes Following Hip Arthroscopy

Request for Waiver or Alteration of Authorization

Instructions:

There are two types of waiver of authorization requests. READ THE HELP TEXT below to determine which waiver request is appropriate for your study.

Request for Waiver of Authorization for Recruitment Only

This option must only be used if you are reviewing PHI in order to identify eligible participants BEFORE approaching them to obtain consent and authorization. All other waiver requests must be entered below.

Other Requests for Waivers of Authorization:

- *Click "Add" below to add a new waiver request to this application.*
- *Click the waiver name link to edit a waiver that has already been created.*
- *To delete a waiver request, contact the IRB.*

| | Date Created | Type of Request | Purpose of Waiver Request |
|----------------------|---------------------|-------------------------|---|
| View | 12/29/2016 | Waiver of Authorization | this study is a database review, no patients will be contacted. |

IRB_00098713

Created: 12/29/2016 4:06 PM

View: IRB Smart Form

PI: Travis Maak MD

Submitted:

- Request for Section: Waiver of Authorization

Title: The Effects of Pre-operative Evaluation Variables on Health Care Costs and Patient Outcomes Following Hip Arthroscopy

Request for Waiver or Alteration of Authorization

1. Purpose of the Waiver Request:

Briefly state or summarize the purpose of this waiver (e.g., record review for recruitment, waive signature, chart review for all data collection, etc.)

this study is a database review, no patients will be contacted.

2. Type of Request:

Waiver of Authorization

3. List the identifying information you plan to collect or keep a link to (e.g. names, dates, or identification numbers such as social security numbers or medical record numbers, etc).

Patient ID
DOB
Race/ethnicity
Gender
Insurance type
CPT codes
ICD diagnosis and procedure codes
urban/rural designation

A table of requested APCD fields is attached in Documents and Attachments (highlighted fields). No identifiable information is being requested. All dates requested will include only month and year rather than full date. PPR will provide urban/rural designation in place of zip code data.

PPR will provide unique substitute ID numbers for the following: Member_ID, Person_ID, Provider_Aux_ID and Payer_Cd.

4. Explain why the *PHI* to be used or disclosed is the minimum necessary to accomplish the research objectives:

Because this study is looking at what factors influence the success/failure rate of hip arthroscopy as well as total cost, without access to the above PHI the research could not be conducted.

5. Explain why the research could not practicably be conducted without the waiver of authorization. For example, complete the following sentence: "If I had to obtain authorization, the research could not be conducted because..."

If we had to obtain authorization the research could not be conducted because It would be impracticable for the investigator to contact every patient that underwent a hip arthroscopy in Utah. Furthermore, all data will be collected in a retrospective manner.

6. Describe your plan to protect the identifiers from improper use and disclosure, and indicate where the *PHI* will be stored and who will have access:

All data collected will be kept in password-protected electronic file that is available only to the investigators listed on the protocol. This file will be stored on the University of Utah Orthopaedic Center's secure server.

7. The identifiers must be destroyed at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such

retention is otherwise required by law. Describe how and when you will destroy the identifiers, or justify their retention:

For VA research, identifiers used for the study must be stored and protected as part of the research record indefinitely. See the VA Records Retention Policy for further details.

Following completion of the study (with anticipated publication of results in a peer reviewed journal), we will delete/remove the electronic file that contains the data used for the study.

8. Describe the measures you will take to ensure the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research approved by the IRB:

Only authorized research staff and investigators will have access to the PHI. No PHI will be disclosed to any person or entity, except as required by law, for authorized oversight of the research study, or for other research approved by the IRB.

IRB_00098713

Created: 12/29/2016 4:06 PM

View: 8. Resources & Responsibilities

PI: Travis Maak MD

Submitted:

Section: Resources and Responsibilities

Title: The Effects of Pre-operative Evaluation Variables on Health Care Costs and Patient Outcomes Following Hip Arthroscopy

8. Resources and Responsibilities

1. State and justify the qualifications of the study staff:

The investigator should ensure that any individual to whom a task is delegated is qualified by education, training, and experience to perform the delegated task. A qualified physician should be responsible for all medical-related decisions and care. You may include a summary of delegated tasks to qualified study staff. You do not need to enter specific staff names, but may use titles such as "sub-investigators", "study coordinators", and "research assistants".

The PI is an orthopedic surgeon at the University of Utah Department of Orthopaedics and is qualified to make all medical-related decisions. The sub-I has a PhD in economics and specializes in healthcare cost and utilization analysis, healthcare financing, healthcare delivery systems, economic evaluations such as cost-effectiveness analysis and medical decision analysis, and will be responsible for accessing data from the APCD and data analysis. The study coordinator will be responsible for assisting the PI/sub-I as necessary. All members of the study team have experience with research and have completed CITI and HIPAA training.

2. Describe the training that study staff and investigators will receive in order to be informed about the protocol and understand their research-related duties and functions:

Such training may include regular meetings with the investigator(s) to discuss progress of the study, training to perform specific study procedures (e.g. screening, informed consent, examinations, etc.), and training on regulatory requirements and proper conduct of a research study. Investigators should maintain documentation of all training received by study staff.

The study team will have an initial meeting to ensure that all members understand the protocol and know their roles and responsibilities with the study. After the initial meeting, the study team will have regular meetings to discuss the progress of the study, any issues with the conduct of the study, and to ensure that everyone is informed with any changes or modifications to the research study or the members' roles and responsibilities.

3. Describe the facilities where the research activities will be performed (e.g. hospitals, clinics, laboratories, classrooms/schools, offices, tissue banks, etc.).

This includes locations and facilities that are supporting the research, but do not need IRB approval to cover their activities (i.e., the facility is not 'engaged in research').

Offices at the University of Utah Department of Orthopaedics and the department of Study Design and Statistical Analysis.

4. Describe the medical or psychological resources available at this site (and other participating sites, if applicable) that participants might require as a consequence of the research. If not applicable, please state.

Such resources may include emergency medical care, genetic counseling, HIV counseling, psychological counseling, patient referrals, etc.

not applicable

IRB_00098713

Created: 12/29/2016 4:06 PM

PI: Travis Maak MD

Submitted:

View: 9. Documents and Attachments
Section: Documents and Attachments

Title: The Effects of Pre-operative Evaluation Variables on Health Care Costs and Patient Outcomes Following Hip Arthroscopy

Documents and Attachments

If any of your documents (such as investigational brochures, sponsor protocols, advertisements, etc.) are not available in an electronic format, please scan and save them as PDF files or contact our office for assistance.

Naming Documents: Please use the title field to clearly indicate the content of each form. The name you enter will be listed on your approval letter. Use names that will differentiate from earlier versions.

Examples:

- Consent Document Control Group 04/14/05
- Consent Document Treatment Group 4/14/05
- Sponsor Protocol 04/14/05 Version 2
- Assent Document (Highlighted Changes)

[Apple/Macintosh Users: MS Word documents must have a .doc file extension. See ERICA home page for instructions.](#)

[Print View: IRB Draft Protocol Summary](#)

eProtocol Summary:

| Name | Version | Date Created | Date Modified | Date Approved |
|-------------------------------|---------|--------------|---------------|---------------|
| There are no items to display | | | | |

Consent Documents, Consent Cover Letters, Consent Information Sheets, Consent Scripts, etc.:

(You must use the current MS Word IRB template to allow watermark approval)

| Name | Version | Date Created | Date Modified | Date Approved |
|-------------------------------|---------|--------------|---------------|---------------|
| There are no items to display | | | | |

Parental Permission Documents:

(You must use the current MS Word IRB template to allow watermark approval)

| Name | Version | Date Created | Date Modified | Date Approved |
|-------------------------------|---------|--------------|---------------|---------------|
| There are no items to display | | | | |

Assent Documents:

(You must use the current MS Word IRB template to allow watermark approval)

| Name | Version | Date Created | Date Modified | Date Approved |
|-------------------------------|---------|--------------|---------------|---------------|
| There are no items to display | | | | |

VA Consent Documents:

(You must use the current MS Word IRB template to allow watermark approval)

| Name | Version | Date Created | Date Modified | Date Approved |
|------|---------|--------------|---------------|---------------|
|------|---------|--------------|---------------|---------------|

There are no items to display

Surveys, Questionnaires, Interview Scripts, etc.:

| Name | Version | Date Created | Date Modified | Date Approved |
|------|---------|--------------|---------------|---------------|
|------|---------|--------------|---------------|---------------|

There are no items to display

Full Protocol (company protocol, sponsor protocol, investigator-initiated protocol, etc.):

A full protocol must be provided if (a) the study is industry sponsored, or (b) if the study is an investigator-initiator, investigational drug or device trial.

| Name | Version | Date Created | Date Modified | Date Approved |
|------|---------|--------------|---------------|---------------|
|------|---------|--------------|---------------|---------------|

There are no items to display

Investigational Brochure (IB) for Investigational Drug or Drug/Device Package Insert:

| Name | Version | Date Created | Date Modified | Date Approved |
|------|---------|--------------|---------------|---------------|
|------|---------|--------------|---------------|---------------|

There are no items to display

Grant Application:

| Name | Version | Date Created | Date Modified | Date Approved |
|------|---------|--------------|---------------|---------------|
|------|---------|--------------|---------------|---------------|

There are no items to display

Literature Cited/References:

Provide a list of references in a SINGLE document. A list of references is not required if provided in an attached protocol or grant application.

| Name | Version | Date Created | Date Modified | Date Approved |
|------|---------|--------------|---------------|---------------|
|------|---------|--------------|---------------|---------------|

| | | | | |
|----------------------|------|-------------------|-------------------|--|
| APCD References.docx | 0.01 | 2/10/2017 2:53 PM | 2/10/2017 2:53 PM | |
|----------------------|------|-------------------|-------------------|--|

Principal Investigator's Scholarly Record (CV/Resume):

If not displayed, please attach a copy of the Principal Investigator's CV, resume, or other documentation that will demonstrate a scholarly record suitable for this kind of study.

| Name | Version | Date Created | Date Modified | Date Approved |
|------|---------|--------------|---------------|---------------|
|------|---------|--------------|---------------|---------------|

| | | | | |
|---------|------|--------------------|--------------------|--|
| Maak CV | 0.01 | 2/26/2014 11:04 AM | 2/26/2014 11:04 AM | |
|---------|------|--------------------|--------------------|--|

Faculty Sponsor's Scholarly Record (CV/Resume):

If applicable.

| Name | Version | Date Created | Date Modified | Date Approved |
|------|---------|--------------|---------------|---------------|
|------|---------|--------------|---------------|---------------|

There are no items to display

Other Stamped Documents:

Only attach documents here as directed by the IRB, such as the Data/Information Request Form for UUHSC EDW.

| Name | Version | Date Created | Date Modified | Date Approved |
|------|---------|--------------|---------------|---------------|
|------|---------|--------------|---------------|---------------|

There are no items to display

Recruitment Materials, Advertisements, etc.:

| Name | Version | Date Created | Date Modified | Date Approved |
|------|---------|--------------|---------------|---------------|
|------|---------|--------------|---------------|---------------|

There are no items to display

Other Documents:

| Name | Version | Date Created | Date Modified | Date Approved |
|------|---------|--------------|---------------|---------------|
|------|---------|--------------|---------------|---------------|

| | | | | |
|--|------|-------------------|-------------------|--|
| UPDB_APCD_Extract_Data_Use_Guide_20170104.xlsx | 0.01 | 3/29/2017 3:13 PM | 3/29/2017 3:13 PM | |
|--|------|-------------------|-------------------|--|

IRB_00098713

Created: 12/29/2016 4:06 PM

PI: Travis Maak MD

Submitted:

View: 10.
Ancillary Applications
Section: Ancillary Applications

Title: The Effects of Pre-operative Evaluation Variables on Health Care Costs and Patient Outcomes Following Hip Arthroscopy

Ancillary Application

This page should be used for submitting human research applications to the following ancillary committees:

Resource for Genetic Epidemiology (RGE) for the use of the Utah Population Database (UPDB)

Phone: 801-581-6351

Website: <http://www.research.utah.edu/rge/index.html>


Radiological Drug Research Committee Human Use Subcommittee (RDRC-HUS)

Phone: 801-581-6141

Website: <http://www.rso.utah.edu/policies/RDRC.pdf>

Instructions for Completing Ancillary Application

1. Click on the name of the study below. The ancillary application will appear.
2. Complete all pages of the ancillary application by clicking "Continue" after each page.
3. When you finish the ancillary application, you will be returned to the IRB New Study Application. If there is more than one ancillary application that needs to be completed, you must complete these steps for each application.
4. Complete the remaining pages of the IRB application.
5. When the PI submits the IRB application, the ancillary application will be submitted also. All ancillary committee reviews will be completed BEFORE the study is sent to the IRB for review. Reviews are not conducted concurrently.

| ID | Name | Date Submitted | Status |
|--|---|----------------|------------|
|  RGE_00002543 | The Effects of Pre-operative Evaluation Variables on Health Care Costs and Patient Outcomes Following Hip Arthroscopy | | Pre Review |

IRB_00098713

Created: 12/29/2016 4:06 PM

View: 12. Finish
Instructions

PI: Travis Maak MD

Submitted: Section: Finish

Title: The Effects of Pre-operative Evaluation Variables on Health Care Costs and Patient Outcomes Following Hip Arthroscopy

Finish Instructions

Finish Instructions

1. To view errors, select the "Hide/Show Errors" option at the top or bottom of the page. If you have errors on your application, you won't be able to submit it to the IRB.
2. Selecting the Finish button will NOT submit the application to the IRB. You MUST select the "Submit" option on the workspace once you've selected the "Finish" button.
3. If your study has a faculty sponsor: Once the PI submits the application, it will be sent to the faculty sponsor for final approval. The IRB cannot review the study until the faculty sponsor submits the application to the IRB.